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10/752,466	01/06/2004	Thomas M. Soukup	H583.104.102	3375

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EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

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09/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/752,466	Applicant(s) SOUKUP ET AL.	
	Examiner FANGEMONIQUE SMITH	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 60-99 is/are pending in the application.
- 4a) Of the above claim(s) _ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/7/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This Office Action is responsive to the Response to the Election/Restriction requirement filed on April 6, 2009 which elects claims 1-59. Examiner has withdrawn election/restriction requirement due to a preliminary amendment which was submitted on January 6, 2004 with the originally filed application. The preliminary amendment cancels claims 1-59 and adds new claims 60-99. Examiner acknowledges the cancellation of claims 1-59; and the addition of new claims 60-99. Claims 60-99 are pending.

Claim Objections

2. Claim 64 is objected to because of the following informalities:
- a. At lines 1 and 2 of claims 61 and 81, it is suggested to modify the limitation “a beam strength of the distal region the stylet wire” to read -- a beam strength of the distal region of the stylet wire --.
 - b. At line 1 of claim 64, it is suggested to modify the limitation “the tension limiter is comprises of” to read -- the tension limiter is comprised of --.
 - c. At lines 1 and 2 of claim 84, it is suggested to modify the limitation “the means for limiting the relative tension force is comprises of” to read -- the means for limiting the relative tension force is comprised of --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 60-79, 82, 85, 86, 94 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 60 recites the limitation "the proximal end portion of the stylet wire" in lines 6 and 7. There is no prior mention of a proximal end portion of the stylet wire in claim 60. Therefore, there is insufficient antecedent basis for this limitation in the claim. Upon rejection of claim 60, any claim depending from claim 60 is also rejected.

6. Claims 62 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the characteristic of the beam strength and how it further limits the claimed invention. The limitation recites "wherein a beam strength of the distal region portion the stylet wire greater than a beam strength of a distal region of the core wire". There is no indication of how the beam strength of the distal region portion is related to the other elements claimed.

7. Claims 64, 65 and 77 recite the limitation "the breaking stress force of the stylet wire" in lines 1-3. There is no prior mention of a breaking stress force of the stylet wire in claims 64, 65 or 77, or in any claim from which claims 64, 65 and 77 depend. Therefore there is insufficient antecedent basis for this limitation in the claim.

Art Unit: 3736

8. Claim 65 recites the limitation "the limit force of the tension limiter" in line 2. There is no prior mention of a limit force of the tension limiter in claim 65 or in any claim from which claim 65 depends. Therefore there is insufficient antecedent basis for this limitation in the claim.

9. The term "approximately equal to" in claim 71 is a relative term which renders the claim indefinite. The term "approximately equal to" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, claim 71 is rejected.

10. Claim 74 recites the limitation "having a progressively decreasing depth distally to proximally along the series" in lines 2 and 3. There is no prior mention of a series in claim 74 or in any claim from which claim 74 depends. Therefore there is insufficient antecedent basis for this limitation in the claim.

11. Claim 76 recites the limitation "the stylet assembly" in line 2. Prior to this recitation, a steerable stylet and a stylet wire are disclosed. It is unclear whether this limitation refers to the steerable stylet, the stylet wire or another stylet, rendering the claim indefinite.

12. Claim 85 recites the limitation "the tension limiter" in line 2. There is no prior mention of a tension limiter in claim 85 or in any claim from which claim 85 depends. Therefore there is insufficient antecedent basis for this limitation in the claim.

13. Claim 86 recites the limitation "the adjustable tensioner mechanism" in line 1. Prior to this recitation, a means for applying a relative tension force and a means for limiting the relative tension force are introduced. It is unclear whether the limitation is referring to one of the tension force means described above or if the limitation intends to introduce another tension controlling means, rendering the claim indefinite.

Art Unit: 3736

14. Claim 94 recites the limitation "having a progressively decreasing depth distally to proximally along the series" in lines 2 and 3. There is no prior mention of a series in claim 94 or in any claim from which claim 94 depends. Therefore there is insufficient antecedent basis for this limitation in the claim.

15. Claim 96 recites the limitation "the stylet assembly" in line 2. Prior to this recitation, a steerable stylet and a stylet wire are disclosed. It is unclear whether this limitation refers to the steerable stylet, the stylet wire or another stylet, rendering the claim indefinite.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

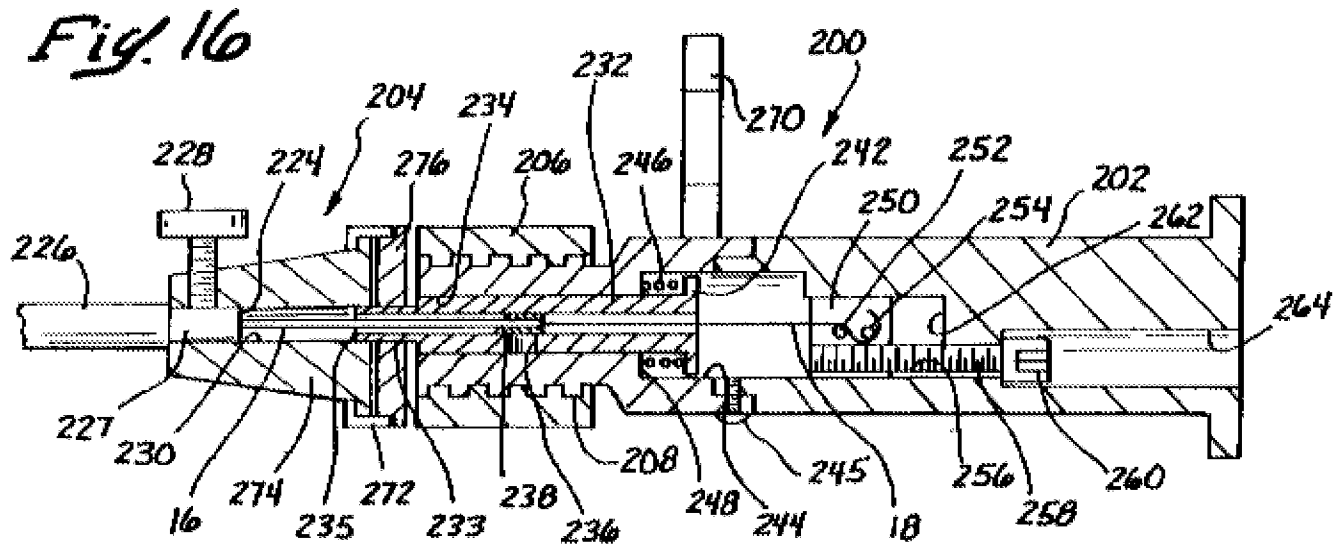
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 60-64, 66, 77-84, 86 and 97-99 are rejected under 35 U.S.C. 102(e) as being anticipated by Cookston et al. (U.S. Patent Number 6,132,390).

In regard to claims 60-64, 66, 77-84, 86 and 97-99, Cookston et al. disclose a deflectable stylet comprising a stylet wire (16) having a plurality of notches (82) and a core wire (18) disposed within a lumen (96) defined by the stylet wire (16) (col. 10, lines 53-67). The core wire (18) has distal portion which is adhesively secured to a section of the stylet wire (16) which is proximate to a distal portion of the stylet wire (16) (col. 7, lines 8-19). The device disclosed by Cookston et

Art Unit: 3736

al. further includes an adjustable tensioner mechanism (206) which is operably connected to the device for applying a tension force between the stylet wire (16) and the core wire (18) (col. 13, lines 12-67). The device includes a tension limiter (258) which is operably arranged for limiting the tension force between the core wire (18) and the stylet wire (16). Cookston et al. disclose the device returning to an original position upon removing tension force from the stylet wire (col. 13, lines 45-67; col. 14, lines 1-18). The tension limiter is capable of limiting the tension force on the device to a limit force that is less than the breaking force of the stylet wire (col. 13, lines 12-21). The tension limiter includes a constant force spring (246) which delivers a maximum tensile strength force which is less than the breaking force of the stylet wire (col. 13, lines 12-67; col. 14, lines 1-49). The tensioner limiter mechanism engages with the compressible spring to increase a force opposing movement of the tensioner. The device disclosed by Cookston et al. is shown in Figure 16 below.



Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 65 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of Erickson et al. (U.S. Patent Number 5,755,695).

In regard to claims 65 and 85, Cookston et al. disclose the features of the Applicant's invention as described above. Cookston et al. do not disclose the breaking stress force of the stylet wire being at least 6 pounds and the limit force of the tension limiter being less than 4 pounds.

Erickson et al. disclose a medical guidewire having a steering handle for guiding a guidewire and catheter through a vessel of a patient. Erickson discloses the use of a handle which permits the guide wire to be manipulated. The handle uses a gripping force of at least 1 pound to maintain a good connection between the handle and the steerable wire. The handle of the Erickson et al. device is used to apply force to the wire and acts as a tension limiting device. The amount of tension applied to the wire of the Erickson et al. device is limited by the amount of force capable of being applied by the handle. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a

Art Unit: 3736

stylet wire, similar to that disclosed by Cookston et al., to include a limiting force, similar to that disclosed by Erickson et al., to minimize the likelihood of the wire breaking during use.

20. Claims 67-74, 76, 87-94 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of Rosenman et al. (U.S. Patent Application Publication Number 2003/0229386).

In regard to claims 67-69, 71-74, 87-89 and 91-94, Cookston et al. disclose the features of the Applicant's invention as described above. Cookston et al. do not specifically disclose information regarding the plurality of notches formed in the distal region of the stylet wire. Rosenman et al. disclose a guide catheter system having a distal tip provided with steering capability. The Rosenman et al. guide catheter system includes slots which are positioned on the distal tip of the device. The slots are arranged into the tube of the distal tip to help control the shape of the distal portion as it bends (paragraph [0025]). Rosenman et al. disclose the slots progressively decreasing in depth from the distal to proximal end of the distal tip. The most distal slots have a diameter approximately equal to the radius of the catheter minus the wall thickness of the catheter. Each slot of the Rosenman et al. device has a longitudinal width of 0.014" and is spaced at a distance of 0.040" from one another. A plurality of separate sets of slots are defined by Rosenman et al. The portion of the slots which decrease in depths comprise between about 5% and about 50% of the slots in the distal tip. Rosenman et al. further disclose a constant decrease in depth between the two adjacent slots that end one set and begin another set (paragraph [0025]). The distance between each set of slots measured from first slot of one set to the first slot of an adjacent set is at least 0.1". Upon defining a set of 10 slots, the set includes a

Art Unit: 3736

portion of notches having a progressively decreasing depth distally to proximally. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire, similar to that disclosed by Cookston et al., to include a plurality of notches with a specific configuration, similar to that disclosed by Rosenman et al., to improve control of the shape of the distal portion of the device. In regard to claims 70, 76, 90 and 96, the combined references of Cookston et al. and Rosenman et al. disclose the features of the Applicant's invention as described above. The combined references do not disclose having three of the most proximal slots having a constant decrease in depth. The combined references also do not disclose having at least two sets of notches having different spacing and widths. Examiner submits as taught by Rosenman et al., it would be desirable to make slots in the distal tip with varying depths to be able to control the shape of the device during use. In effort to better suit the purpose of use, changes such as changing the slot depth dimensions of the device would be obvious variants of the invention as originally taught by Cookston et al. and Rosenman et al. Examiner submits, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the dimensions of the slot depths, including having three slots progressively decrease in depth or having a set of slots differ in width and spacing, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

21. Claims 75 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cookston et al. (U.S. Patent Number 6,132,390) in view of Hata et al. (U.S. Patent Number 6,611,720).

Art Unit: 3736

In regard to claims 75 and 95, Cookston et al. discloses the features of the Applicant's invention as described above. The Cookston et al. reference does not specifically disclose including a set of notches at a different radial position than another set on the distal region of the stylet wire. Hata et al. disclose a deflectable high torque catheter which includes a plurality of staggered rows of slits (col. 3, lines 50-63). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a deflectable stylet comprising a stylet wire, similar to that disclosed by Cookston et al., to include a plurality of notches with a specific configuration, similar to that disclosed by Hata et al., to provide multi-directional deflectability of the distal portion of the device (Hata et al: col. 2, lines 55-64).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FANGEMONIQUE SMITH whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736